Public Health Service
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES m 893 N

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6710

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our ref: 2952492

May 8, 1997

Karen Porrazzo, President
Chain Reactions, Inc.
3701 Clair Dr.
Carmichael, CA 95608

Dear Mrs. Porrazzo:

We are writing to you because between March 26, 1997 and April 7, 1997, Patricia A. Cruz, an investigator from the Food and Drug Administration (FDA) conducted an inspection of your firm and determined that you manufacture and market a product known as "PFT 1-2-3 Personal Fertility and Reproductive Health System. Information was collected during the inspection which revealed serious regulatory problems involving this device.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (Act), the PFT 1-2-3 Personal Fertility and Reproductive Health System is considered to be a medical device because it is used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices obtain marketing clearance for their products from FDA before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records show that you did not obtain marketing clearance before you began offering your product for sale. Between July 1996 and April 1997, your firm manufactured and distributed approximately [redacted] PFT 1-2-3 Personal Fertility and Reproductive Health System devices without clearance from FDA.

Because you do not have marketing clearance from FDA, marketing your product is a violation of the law. In legal terms, the product is misbranded under section 502(o) of the Act because you did not submit information that shows your device is substantially equivalent to other devices that are legally marketed.

The inspection also revealed that the PFT 1-2-3 Personal Fertility and Reproductive Health System devices are adulterated within the meaning of 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) Regulation for Medical Devices as set forth in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. You do not have a Device Master record for the PFT 1-2-3 Personal Fertility and Reproductive Health System. [21 CFR 820.181]

2. You do not have device history records for approximately 3,000 PFT 1-2-3 Personal Fertility and Reproductive Health System devices manufactured and distributed since July of 1996. [21 CFR 820.184, 820.160]

3. You have not documented finished device testing results for the PFT 1-2-3 Personal Fertility and Health System devices released for distribution to ensure that acceptable device specifications were met. [21 CFR 820.184]

4. There is no assurance that the components (i.e., lenses, glass beads, and testing units) received by your firm to manufacture the PFT 1-2-3 Personal Fertility and Reproductive Health System devices have been inspected and accepted to ensure they meet specifications prior to manufacturing. Chain Reactions, Inc. does not maintain records documenting the acceptance and rejection of components. [21CFR 820.80]

5. You have not conducted investigations into complaints that the PFT 1-2-3 Personal Fertility and Reproductive Health System failed to perform as intended. [21 CFR 820.162 and 820.198]

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and the FDA483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonable related will be cleared until the violations have been corrected. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. Please include in your response an explanation of each step being taken to identify and correct any underlying systems problems which will assure that similar violations will not recur. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the date on which the corrections will be completed.

Your response should be sent to Andrea P. Scott, Compliance Officer, Food and Drug Administration, 96 North Third St., Suite 325, San Jose, CA 95112.

You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-(800)638-2041 or through the Internet at http://www.fda.gov.

Sincerely yours,

Patricia C Ziobro

Patricia C. Ziobro
District Director
San Francisco District